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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,104	09/27/2000	Alan P. Kozikowski	ZAA-012.01	6012

25181 7590 10/31/2003

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EXAMINER

HUANG, EVELYN MEI

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 10/31/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/671,104

Applicant(s)

KOZIKOWSKI ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 27-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 27-44 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. Claims 1-18, 27-44 are pending. Claims 19-26, 45-59 have been canceled according to the amendment filed on 2-5-2003.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-27-2003 has been entered. The amendment filed on 7-7-2003 has been entered.

Claim Rejections - 35 USC § 112(2)

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18, 27-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1, 7, 11, 27, 33, 37,

- Definition of R₁₄, 'R' in 'R₉C(O)OR , OC(O)R' is not defined and is therefore indefinite.
- It is confusing to have two sets of definitions for R₈ and R₉ within the same claim: the R₈ and R₉ within the original definition for R₂-R₁₃, and the newly added definitions for R₈ and R₉.
- Definition of R₁, R₂-R₁₃, the meaning of 'heteroaryl' is unclear because a definition of 'heteroaryl' is not found in the specification, whereas

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according the definition on page 8 of the specification, the aromatic 5-7-membered 'aryl', 'which may include zero to 4 heteroatoms' would have included the 'heteroaryl' as ordinarily known to one of ordinary skill in the art. Clarification is required.

- b. Claims 3, 4, 9, 10, 13, 14, 29, 30, 35, 36, 'alkoxy' in claims 3, 9, 13, 29, 35, and 'methoxy' in claims 4, 10, 14, 30, 36 have no antecedent basis in the respective base claims 1, 7, 11, 27, 33.

The rejection is applicable to claims dependent thereon.

Claim Rejections - 35 USC § 112(1)

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18, 27-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant maintains that the structures in the amended claims correspond to groups originally presented in the claims and are not new matter. However, support for the amendment in the specification has not been specifically recited. Furthermore, R8, R9, Q1 and Q2 as defined are not described in the specification.

Claim Rejections - 35 USC § 112(1)

5. The 112 first paragraph rejection set forth in the office action mailed on 9-9-2002 is maintained for claims 1-4, 7-18, 27-30, 33-44 for reasons of record.

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Applicant has submitted references, Exhibits A-D, to show that certain tropane compounds were available at the time of the filing of the application.

The submitted references show 2, or at the most 4 substituents on the tropane ring, which is quite different from the instant 14 substituents, each of which may be optionally substituted aryl, heteroaryl, cycloalkyl, polycyclic, heterocyclic etc. , wherein 'substituted' is 'contemplated to include all permissible substituents of organic compounds.....the invention is not intended to be limited in any manner by the permissible substituents of organic compounds' (page 9 of the specification, lines 16-25). The preparation of the 8 example compounds, however, is limited to A being a double bond, R1 is phenyl, substituted phenyl, naphthyl or furyl, R₂ to R₁₃ are hydrogen, R14 is a carboxylate (Fig. 3), the scope of the claims therefore does not commensurate with that of the objective enablement. Undue experimentation would be required for the skill in the art to make these highly substituted compounds, (where the ring substituents are further substituted by bulky substituents), especially when the starting materials have not been disclosed.

Furthermore, there is no assurance that compounds of such diverse structures would be useful in inhibiting *any* monoamine transporters, and useful in treating *any* disorders or conditions caused by deficiency of any type of monoamine, or any neurodegenerative disorder, including Alzheimer's disease, which as of now, has not been treated with an monoamine reuptake inhibitor.

In view of the high degree of unpredictability in the art, the limited examples and the scope of the claims does not commensurate with that of the objective enablement, one of ordinary skill in the art would not be able to make and use the invention as claimed without undue experimentation except for making and using the compound wherein R1 is aryl or heteroaryl, R2 to R13 being hydrogen, for inhibition of monoamine reuptake and for treating depression.

Conclusion

6. The compound of claims 5, 6, 31, 32, its composition, its method for inhibiting monoamine reuptake and its method for treating depression would be allowable if the 112 second paragraph rejection and 112 first written description rejection were overcome.

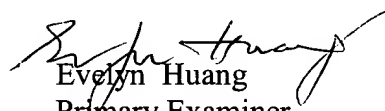
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The closest prior art is Kozikowski (6150376) or Scheel-Kruger (WO 97/16451, PTO-1449). Kozikowski (column 13, lines 18 to 53; column 18, compounds 30, 31, 40; column 57, compounds 6.34. 6.35) or Scheel-Kruger (pages 4-5; pages 24-25, Examples 3, 4, 5) discloses a tricyclic compound derived from tropane, and the composition thereof, are described. However, the prior art compound is a front-bridged or back-bridged compound whereas the instant is N-3-bridged compound.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Evelyn Huang
Primary Examiner
Art Unit 1625
